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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,987	09/17/2001	Stefan Bauer	C1041/7016 (AWS)	7680
23628	7590	06/08/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/954,987	<b>Applicant(s)</b> BAUER ET AL.	
	<b>Examiner</b> Carolyn L Smith	<b>Art Unit</b> 1631	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 10 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 13,18,19 and 21.

Claim(s) withdrawn from consideration: 2-12,16,20,22,26,40,44,62,80,98,114 and 120.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 01282004.
10. ☒ Other: attached interview summary from 5/19/04

Continuation of 2. NOTE: Due to the addition of new issues, NEW MATTER, failure to place the application in better form for appeal, and presenting additional claims while failing to cancel a corresponding number of finally rejected claims, the proposed amendment will not be entered. Therefore, all of the rejections stated in the FINAL rejection, mailed 2/5/04, are maintained.

If the proposed amendment had been entered, the newly added phrase "said polypeptide comprising an amino acid sequence of SEQ ID NO: 6 except for substitution of amino acids 269-274 of SEQ ID NO: 6 with amino acids 269-274 of SEQ ID NO: 3" in proposed amended claim 13 presents a new issue. The term "gene" (line 1) and the phrase "comprising a reporter gene operatively linked to a promoter sensitive to NF-kB" (lines 2-3) in proposed amended claim 21 present new issues. The phrase "wherein the host cell is a 293 fibroblast cell" in proposed new claims 121 and 122 presents a new issue. The broad support given by applicants of residues being interchanged between human and murine TLR9 (page 106, last paragraph), does not provide specific support for "except for substitution of amino acids" (proposed amended claim 13) which differs in scope and would therefore be considered NEW MATTER. If the amendment had been entered, the 35 USC 112, first paragraph, lack of written description rejection would require further consideration due to the presence of NEW MATTER in the rejected proposed claim 13 as well as the new reference to SEQ ID NO: 6 which was not originally considered in previous prosecution. If the amendment had been entered, the 35 USC 112, second paragraph, rejection would have been removed.

*John H. Marschel* 6/6/04  
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ATTORNEY